

REMARKS

Claims 1-17, 19-22, 25-65, 69-80 and 82-115 are pending in the current application. Claims 2, 6, 8, 14-15, 87 and 95 have been amended. Claims 12, 16, 19, 21, 25-44, 46-49, 53, 62-65, 69-80, 84, 89, 91-92, 94, 97, 99-102, and 104-113 were withdrawn by the Examiner as drawn to a non-elected invention or a non-elected species. No new claims have been added.

Claim Rejections under 35 USC § 112

Claim 2 was rejected under 35 U.S.C. § 112 as being indefinite due to the phrase “preferably.” Applicants respectfully submit that this rejection is moot in light of the amendment to Claim 2 and request withdrawal of this rejection.

Claim Rejections under 35 USC § 102

Claims 1-5, 7-15, 17, 20, 22, 50-52, 54-61, 82, 85, 87, 90, 93, 95, 96, 98, 103, and 114-115 are not anticipated by Peak et al.

Claims 1-5, 7-15, 17, 20, 22, 50-52, 54-61, 82, 85, 87, 90, 93, 95, 96, 98, 103, and 114-115 were rejected under 35 U.S.C. § 102(b) as being anticipated by Peak et al. (WO 2001/055182). Applicants respectfully traverse this rejection.

Peak et al. does not disclose an immunogenic composition comprising at least one Neisserial autotransporter antigen and at least one different antigen, wherein the at least one different antigen is selected from the following categories:

a) at least one Neisserial adhesin; b) at least one Neisserial toxin; c) at least one Neisserial Fe acquisition protein; or d) at least one Neisserial membrane associated protein, as claimed by Applicants.

Peak et al. relates to proteins comprising conserved regions of *Neisseria meningitidis* surface antigen NhhA (Title). Specifically, Peak et al. is “broadly directed to isolated proteins having conserved amino acids of NhhA polypeptides.” (page 2, lines 31-32). Example 2, cited by the Examiner, relates to over-expression of NhhA protein “by making an expression construct wherein the *nhhA* gene is operably linked to a promoter.” (page 41, lines 13-15). “In an eleventh aspect of the invention, there is provided a pharmaceutical composition comprising an isolated

protein according the first mentioned aspect.” (page 6, lines 5-7, emphasis added).
“In a first aspect, the invention provides an isolated protein comprising twelve or more contiguous conserved amino acid sequences of an Nhha polypeptide, said isolated protein excluding wild-type NhhA polypeptides.” (page 3, lines 4-6).

Peak et al. does not teach an immunogenic composition comprising at least one Neisserial autotransporter antigen and at least one different antigen, wherein the at least one different antigen is selected from the following categories: a) at least one Neisserial adhesin; b) at least one Neisserial toxin; c) at least one Neisserial Fe acquisition protein; or d) at least one Neisserial membrane associated protein, as claimed by Applicants. No support is provided in the Office Action for the Examiner’s statement “the immunogenic composition disclosed by Peak et al comprised an overexpression of Nhha/Hsf, and that it was inherently in the presence of other Neisserial adhesion proteins or toxins or Fe acquisition proteins or membrane associated proteins.” (page 3 of the Office Action). In contrast, the pharmaceutical compositions described in Peak et al. relate to an isolated protein comprising twelve or more contiguous conserved amino acid sequences of an Nhha polypeptide. It is the use of the polypeptide, fragment, variant or derivative of their invention as actives in a pharmaceutical composition that is contemplated by Peak et al. (page 32, lines 7-9).

Furthermore, the composition of Peak et al. does not necessarily contain another Neisserial adhesin, protein, toxin, Fe acquisition protein or membrane associated protein as suggested by the Office Action. Inherent anticipation requires that the missing descriptive material is “necessarily present” in the prior art. *Continental Can Co. USA, Inc. v. Monsanto*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). Under the principles of inherency, to anticipate prior art must necessarily function in accordance with, or include, the claimed limitations to anticipate. *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). The components of Applicants’ claimed composition are not necessarily present in Peak et al.

Peak et al. do not expressly or inherently anticipate Applicants’ claimed invention. Applicants respectfully request that this rejection be withdrawn.

Claim 1 is not anticipated by U.S. Publication 2005/232936.

Claim 1 was rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Publication 2005/232936. Applicants respectfully traverse this rejection.

U.S. Publication 2005/232936 does not teach an immunogenic composition comprising at least one Neisserial autotransporter antigen and at least one different antigen, wherein the at least one different antigen is selected from the following categories: a) at least one Neisserial adhesin; b) at least one Neisserial toxin; c) at least one Neisserial Fe acquisition protein; or d) at least one Neisserial membrane associated protein, as claimed by Applicants.

U.S. Publication 2005/232936 relates to meningococcus adhesins NadA, App, and ORF 40 (Title) and “is in the field of biochemistry and, in particular, the biochemistry of the bacteria in the genus *Neisseria* (e.g. *N. meningitidis* and *N. gonorrhoeae*).” (page 1, Technical Field). Claim 32, cited by the Examiner on page 4 of the Office Action, does not disclose “an immunogenic composition comprising an outer membrane vesicle and an autotransporter antigen, NadA,” as suggested by the Examiner. Instead, Claim 32 relates to “[a] method for preparing an outer membrane vesicle (OMV) from a non-Neisserial host cell, characterised in that said cell expresses a gene encoding App, ORF40 or NadA protein.” (page 59). Furthermore, Claim 32 relates to an OMV from a non-Neisserial host cell. Specifically, *E.coli* is contemplated in U.S. Publication 2005/232936 (page 5, paragraph [0084]).

U.S. Publication 2005/232936 does not teach each and every element as set forth in Claim 1. Therefore, it does not anticipate Claim 1. M.P.E.P. 2131. Applicants respectfully request that this rejection be withdrawn.

Claims 1-15, 17, 20, 22, 50-52, 54-61, 82-83, 85-87, 90, 93, 95, 96, 98, 103 and 114-115 are not anticipated by U.S. Publication 2003/0215469.

Claims 1-15, 17, 20, 22, 50-52, 54-61, 82-83, 85-87, 90, 93, 95, 96, 98, 103 and 114-115 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Publication 2003/0215469. Applicants respectfully traverse this rejection.

U.S. Publication 2003/0215469 relates to a “multicomponent meningococcal vaccine” (Title) and “[a] composition is provided comprising *N. Meningitidis* outer

membrane vesicles, wherein said outer membrane vesicles are enriched with at least one antigenic component.” (Abstract). The Examiner suggests on page 4 of the Office Action that U.S. Publication 2003/0215469 discloses “an immunogenic composition comprising an outer membrane vesicle and an autotransporter antigen, Hsf. (See claim 8).” It is respectfully submitted that Hsf is not disclosed in the priority documents claimed by U.S. Publication 2003/0215469 and, therefore, the Hsf subject matter is entitled to the filing date of the continuation-in-part December 17, 2002. It is respectfully submitted that the Hsf subject matter is not prior art against Applicants’ instant application.

Applicants respectfully request that this rejection be withdrawn.

Claim Rejections under 35 USC § 103

Claims 1-15, 17, 20, 22, 45, 50-52, 54-61, 82, 83, 85-88, 90, 93, 95, 96, 98, 103, and 114-115 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Publication 2003/0215469 or Peak et al. in view of U.S. Publication 2007/087018. Applicants respectfully traverse this rejection.

First, the Examiner states that:

The claim is drawn to an immunogenic composition comprising at least one Neisserial autotransporter antigen and at least one different antigen, wherein the at least one different antigen is selected from the following: at least one Neisserial adhesin, at least one Neisserial toxin, at least one Neisserial Fe acquisition protein or at least one Neisserial [membrane] associated protein, wherein OMP 85 is upregulated.

Only Claim 86 recites “wherein OMP85 is upregulated in one of the blebs.”

Secondly, the Hsf subject matter in U.S. Publication 2003/0215469 is not prior art against Applicants’ instant application, as discussed above.

Additionally, Peak et al. have not “taught of immunogenic compositions comprising both an autotransporter (Hsf) and various other Neisserial antigens,” as suggested by the Examiner. (page 6 of the Office Action). Peak et al. is “broadly directed to isolated proteins having conserved amino acids of Nhha polypeptides.” (page 2, lines 31-32).

US Publication 2007/087018 relates to "OMP85 proteins of *Neisseria gonorrhoeae* and *Neisseria meningitidis*, compositions containing same and methods of use thereof." (Title). Although the Examiner has suggested that "US Publication 2007/087018 has taught of the desire for including OMP 85 in *Neisseria* immunogenic compositions for eliciting an immunogenic response," (page 6 of the Office Action), no support for this statement is provided. In contrast, US Publication 2007/087018 suggests that "antigens and antibodies of the invention, alone or in combination with other antigens of antibodies of, or directed to, other pathogenic microorganisms may further be used in therapeutic compositions and in methods for treating humans and/or animals with non-symptomatic infection or symptomatic disease caused by *N. gonorrhoeae*, *N. meningitidis* or the other pathogens identified above." (page 12, [0085], emphasis added; see also [0142]).

Applicants respectfully submit that the articulated reasoning to support the conclusion of obviousness is unsupported. It is respectfully requested that this rejection be withdrawn.

CONCLUSION

Should any outstanding issues remain, the Examiner is encouraged to contact Applicants' undersigned representative.

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